Socioeconomic deprivation and surgical outcomes: ISOS and VISION-UK sub-study Statistical analysis plan

Investigators

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Working title

Prospective observational cohort study of socioeconomic deprivation and post-operative outcomes following elective surgery within ISOS and VISION-UK.

Background

Surgery is one of the most common treatments offered by the NHS in secondary care within the UK. One in ten adults has a surgical procedure each year, and the annual number of procedures is increasing steadily, particularly in elderly patients.[1] There are 4.6 million hospital admissions that lead to surgical care every year in England alone (Hospital Episode Data, Department of Health). One in five people in England aged 75 years and over underwent surgery in 2015.[2] Perioperative complications present a substantial burden to healthcare cost due to associated mortality and morbidity.[3-5]

The link between poverty, socioeconomic inequalities and increased mortality is well established.[6] Differences in socioeconomic status have been shown to be associated with increased mortality in a range of diseases as well as incidence of multimorbidity.[7-11] Inequalities in healthcare continue to exist globally.[12] Improvements in healthcare provision in the UK over time such as in cancer care have not been demonstrated across socioeconomic groups with persistent limitations in the most deprived areas.[13] The reasons for this are multifactorial including barriers in accessing healthcare secondary to both financial limitations and geographical distance, variations in availability and quality of services in areas of greater deprivation, differences in lifestyle factors such as smoking, alcohol and dietary, as well as health seeking behaviour.[14-18]

Studies including systematic reviews have demonstrated an association between socioeconomic deprivation on mortality and morbidity after specific types of surgery including colorectal [19], endometrial cancer[20], major elective joint replacement[21], head and neck cancer[22], lung cancer[23], amputation in peripheral artery disease[24]. These observation studies have tended to be carried out in single centres, smaller cohorts or for specific disease indications.

The office for national statistics have published data measuring relative deprivation in small areas in England.[9] The English Indices of Deprivation 2015 is a composite score based on 37 separate indicators. These are grouped into seven distinct domains: income; employment; health and disability; education, skills and training; barriers to housing and other services; crime; living environment.[9] Similarly, Scotland, Northern Ireland and Wales have calculated comparative statistical measures.[25-27] In this paper, we aim to determine if socioeconomic deprivation in England is associated with outcomes after surgery: mortality, in-hospital complications at 30 days, and hospital length of stay. We will also identify clinical factors associated with social deprivation and assess whether adjustment for these factors modify the effect of socioeconomic deprivation on outcomes for a range of surgical categories.

Aim

To describe the distribution of socioeconomic status amongst the ISOS and VISION-UK cohorts undergoing elective surgery and its association with post-operative complications within 30 days (specific endpoints defined below) and death within 3 years.

Objectives

1. To describe socioeconomic status of the study population as measured by index of multiple deprivation quintiles
2. To determine if socioeconomic status is associated with the following outcomes:
    - mortality at 30 days, at 1 year, and at 3 years
    - in-hospital complications at 30 days
    - hospital length of stay

3. To determine if different surgical categories vary for the following outcomes when deprivation is taken into account:
    - mortality at 30 days, at 1 year, and at 3 years
    - 30 day in-hospital mortality
    - hospital length of stay

Data collection

Study cohorts

The International Surgical Outcome Study (ISOS) is an international multi-centre cohort study of perioperative morbidity and mortality in patients undergoing elective surgery (ISRCTN51817007).[9] Data collection occurred during a seven-day period between April and August 2014 in 474 hospitals in 27 countries. All patients admitted to participating centres for elective surgery with a planned overnight stay were eligible. Patients undergoing day-case surgery or radiological procedures were excluded because they followed a dedicated pathway of care. Only patients from England will be included in this secondary analysis, xx hospitals participated in the UK, leading to a sample size of xxx patients. Patients were followed up for a maximum of 30 days after surgery for complications. Mortality data is collected up to 3 years post-operatively.

The Vascular Events in non-cardiac surgery (VISION) study is a prospective, international cohort study designed to evaluate major complications following non-cardiac surgery. Patients are eligible if they are 45 years or older and receiving either general or regional anaesthesia, requiring at least an overnight stay in hospital. The research ethics committee/institutional review board at each site approved the protocol prior to patient recruitment. For this analysis, only patients from England were included, from 4 sites. Detailed and standardised data are collected before surgery, during the patient's hospital stay until discharge, at 30 days, and at one year after surgery.

Sample

The dataset for this secondary analysis includes only patients from England from both the ISOS and VISION-UK cohorts with mortality outcome data.

Definition of key variables

The paper case report forms (CRF) are shown in appendix 1 and 2. Baseline demographics and clinical data for patients will be summarised and presented for each socioeconomic quintile but not subject to statistical testing. The following baseline characteristics will be compared. Numbers (%) or means (SD) and medians (IQR) will be given for each group as appropriate.

Patient characteristics: Age in years, Sex (M/F), Current smoker (Y/N), ASA (I-IV), Comorbidities – Coronary artery disease (Y/N), Diabetes mellitus (Y/N), Metastatic cancer (Y/N), COPD/asthma (Y/N), Heart failure (Y/N), Stroke/TIA (Y/N), pre-operative Haemoglobin level in g/L, pre-operative Creatinine in μmol/L.

Surgical factors: Surgical procedure (Orthopaedic/Breast/Obstetrics and gynaecology/Urology and kidney/Upper gastro-intestinal/Lower gastro-intestinal/Hepato-biliary/Vascular/Head and neck/Plastics and cutaneous/Cardiac/Thoracic/Other), Severity of surgery (Minor/Intermediate/Major), Laparoscopic surgery (Y/N), Cancer surgery (Y/N)

Statistics on relative measures of socioeconomic deprivations are publicly available according to the postcode of the patient's home address. The English Indices of Deprivation 2015 (IMD 2015) based on statistics from 2012 to 2013 will be used. The contribution of each of the seven distinct domains to the overall score is weighted differently, with income and employment deprivation weighted the most, to calculate the Index of Multiple Deprivation (IMD). Lower-Layer Super Output Areas (LSOAs) are small areas designed to be of a similar population size, with an average of approximately 1,500 residents or 650 households. There are 32,844 Lower-layer Super Output Areas (LSOAs) in England which have been divided according to their deprivation rank into 10 equal groups (deciles). Analysis will be carried out by using quintiles of deprivation for LSOAs ranked by IMD in the combined cohort to account for potential disproportionate grouping in different deciles of IMD in our dataset.

Statistical analysis

The analysis will be conducted in two stages. First, we will examine whether deprivation, classified by IMD 2015, is associated with mortality at 30 days, mortality at 1 year, mortality at 3 years, in-hospital complications at 30 days, and hospital length of stay. Mortality data to

3 years is only available for ISOS and so analysis for this outcome is limited to the ISOS cohort. Secondly, we will identify factors which are strongly associated with deprivation (we anticipate these might be smoking and diabetes) and assess whether adjustment for these factors modify the effect of socioeconomic deprivation on outcomes.

Primary analyses

The primary outcome is mortality. Univariable and multivariable logistic regression analyses will be used to test association between socioeconomic deprivation categorised by IMD quintiles and mortality at 30 days, 1 year, and 3 year. The following additional variables will be entered into the multivariable model: Age, Sex, Current smoker, ASA, any type of Comorbid disease, pre-operative Haemoglobin, pre-operative Creatinine. Results will be presented as odds ratios with 95% confidence intervals. Mixed effects logistic regression models using a random intercept for hospital site will be repeated for the primary outcome and included as a sensitivity analysis.

The secondary outcomes include in-hospital complications at 30 days and hospital length of stay. Specific complications include: Surgical site infection, Body cavity infection, Pneumonia, Urinary tract infection, Blood stream infection, Myocardial infarction, Arrhythmia, Pulmonary oedema, Pulmonary embolism, Stroke, Cardiac arrest, Gastro-intestinal bleed, Acute kidney injury, Postoperative bleed, Acute Respiratory Distress Syndrome, Anastomotic leak. A multivariable logistic regression model will be developed using presence of complication as the endpoint and with the same covariates as the primary model. Adjusted odds ratios with 95% confidence intervals will be presented in a table with the incidence of each type of complication expressed as a percentage. Only patients who experience each complication alone will be included to prevent duplication. Sensitivity analyses will be carried out for patients who experience more than one complication and for patients with complications classified as severe. To test association with hospital length of stay and socioeconomic deprivation, a linear regression model will be constructed using the same method as above. The endpoint will be hospital length of stay in days. The independent variables will be same as the primary model. All models based on mixed effects regression modelling with a random intercept for hospital site will be included as a sensitivity analysis as per the primary outcome model.

Secondary analyses

The secondary objective of this paper is to identify how mortality and hospital length of stay vary for different surgical categories when deprivation is taken into account. For this analysis, a Cox proportional hazards model will be constructed with the following covariates: Surgical category, Socioeconomic quintile, hospital length of stay with 30 day mortality as a competing outcome and any other variables which were found to be significantly associated with deprivation in the model above.

Age adjustment

Differences in age was expected between socioeconomic groups and seen when cohort baseline characteristics were examined. As such, all univariable analyses were conducted adjusted for age.

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Figures and tables

Figure 1: STROBE flow diagram of study population

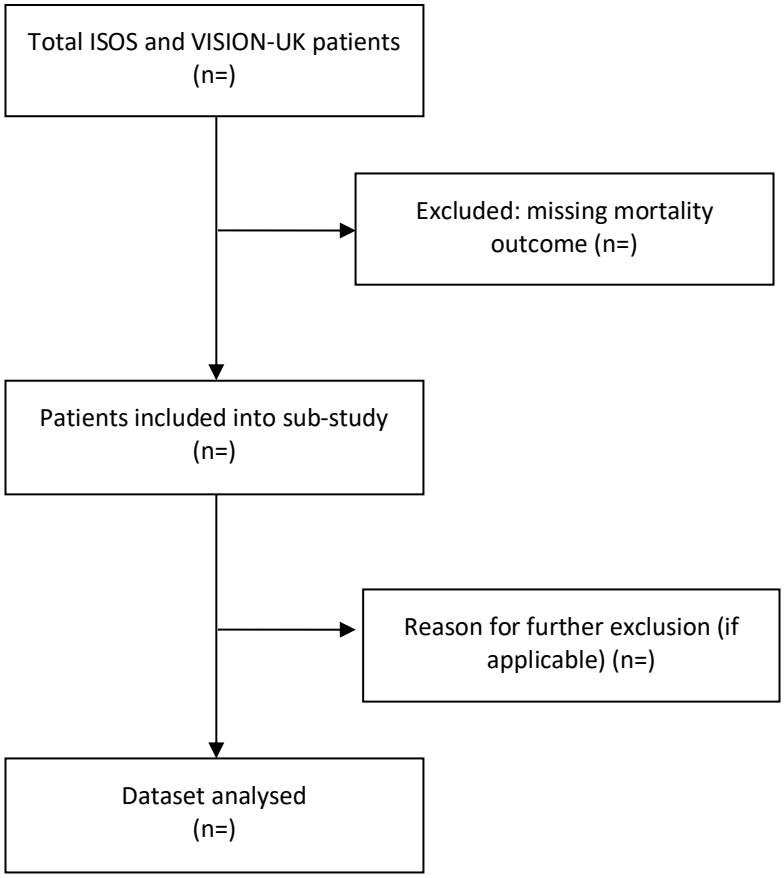

Figure 2: Socioeconomic deprivation and surgical outcomes by geography.

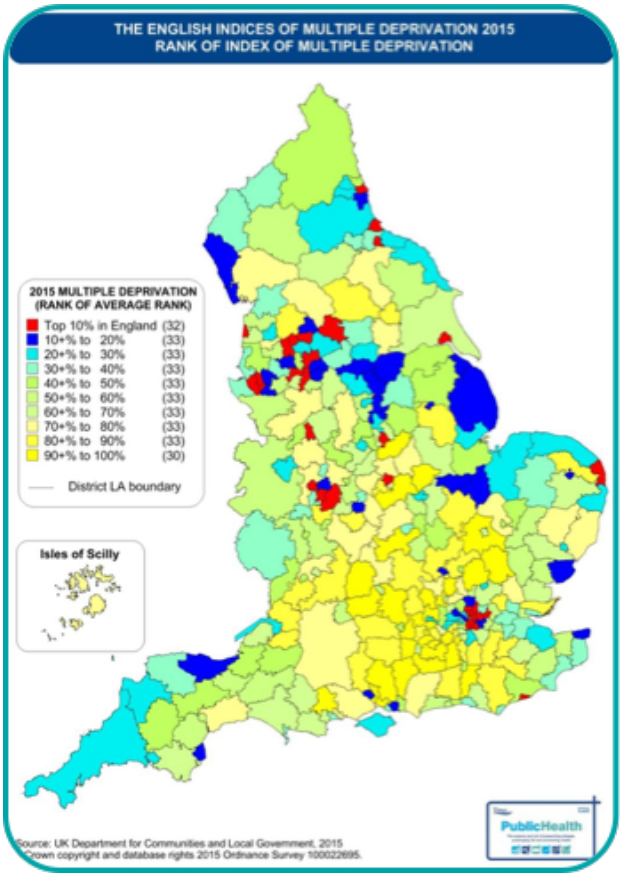

Table 1: Baseline characteristics. All numbers shown in n (%) unless stated otherwise.

	Quintile 1	**Quintile 2**	**Quintile 3**	**Quintile 4**	**Quintile 5**
Age					
Mean (SD)					
Median (IQR)					
Male					
Current smoker					
ASA					
1					
2					
3					
4					
Co-morbid disease					
Coronary artery disease					
Diabetes mellitus					
Metastatic cancer					
COPD/asthma					
Heart failure					
Cirrhosis					
Stroke					
Other					
Pre-operative Haemoglobin					
Pre-operative Creatinine					
Surgical procedure					
Orthopaedic					
Breast					
Obstetrics and gynaecology					
Urology and kidney					
Upper gastro-intestinal					
Lower gastro-intestinal					
Hepato-biliary					

Vascular					
Head and neck					
Plastics and cutaneous					
Cardiac					
Thoracic					
Other					
Severity of surgery					
Minor					
Intermediate					
Major					

Table 2: Association between deprivation and mortality

Socioeconomic quintile	Mortality (n, %)	Univariable		Multivariable	
		Odds ratio (95% CI)	P value	Odds ratio (95% CI)	P value
30 day mortality					
Quintile 1					
Quintile 2					
Quintile 3					
Quintile 4					
Quintile 5					
1 year mortality					
Quintile 1					
Quintile 2					
Quintile 3					
Quintile 4					
Quintile 5					
3 year mortality					
Quintile 1					
Quintile 2					
Quintile 3					
Quintile 4					
Quintile 5					

Figure 3: Kaplan-Meier graph of mortality categorised by socioeconomic deprivation

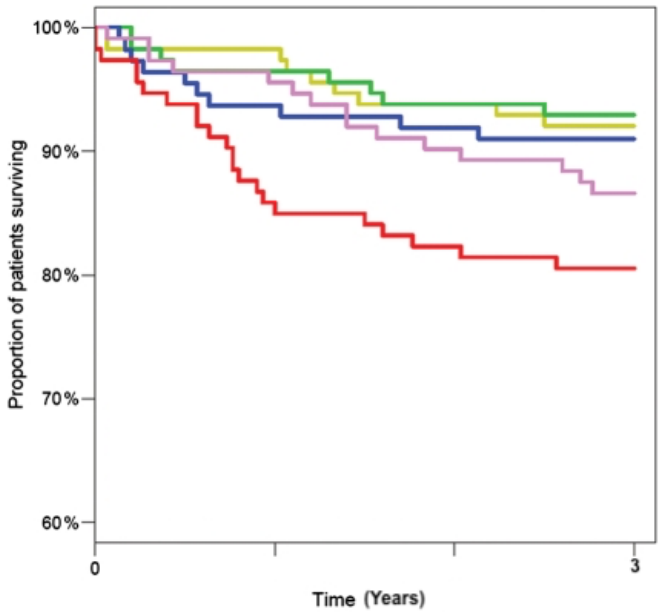

Table 3: Association between deprivation and in-hospital complications

Socioeconomic quintile	**In-hospital complication (n,%)**	**Univariable**		**Multivariable**	
		Odds ratio (95% CI)	**P value**	**Odds ratio (95% CI)**	**P value**
Quintile 1					
Quintile 2					
Quintile 3					
Quintile 4					
Quintile 5					

Figure 4: Kaplan-Meier graph of in-hospital complications categorised by socioeconomic deprivation

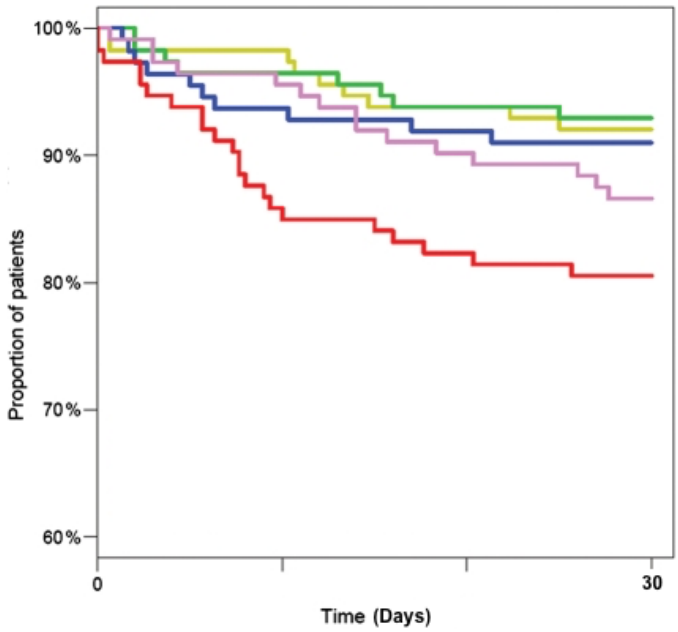

Table 4: Association between deprivation and length of hospital stay

Socioeconomic quintile	**Univariable**		**Multivariable**	
	Length of hospital stay (95% CI)	**P value**	**Length of hospital stay (95% CI)**	**P value**
Quintile 1				
Quintile 2				
Quintile 3				
Quintile 4				
Quintile 5				

Table 5: Association between surgical outcomes in different surgical categories (adjusted for deprivation)

Surgical procedure	Incidence of complication (n, %)	In-hospital mortality		In-hospital complication	
		Unadjusted odds ratio (95% CI)	Adjusted* odds ratio (95% CI)	Unadjusted odds ratio (95% CI)	Adjusted* odds ratio (95% CI)
Orthopaedic					
Breast					
Obstetrics and gynaecology					
Urology and kidney					
Upper gastro-intestinal					
Lower gastro-intestinal					
Hepato-biliary					
Vascular					
Head and neck					
Plastics and cutaneous					
Cardiac					
Thoracic					
Other					

***adjusted for socioeconomic quintiles**

Appendix 1 CRF for ISOS

Patient name: ..... Date of birth: dd/mm/yyyy

International Surgical Outcomes Study Case Record Form v2.3

For use with Outcomes definitions guide

Age ☐☐☐ years Gender ☐ M ☐ F Current smoker ☐ Y ☐ N

ASA ☐ I ☐ II ☐ III ☐ IV Black ethnicity (eGFR) ☐ Y ☐ N

Chronic Disease (*tick all that apply*):

- ☐ Coronary Artery Disease
- ☐ Diabetes Mellitus
- ☐ Metastatic cancer
- ☐ COPD / Asthma
- ☐ Heart Failure
- ☐ Cirrhosis
- ☐ Stroke
- ☐ Other

Most recent blood results (no more than 28 days before surgery):

Haemoglobin ☐☐☐.☐ g/L Leucocytes ☐☐.☐ x10^9/L

Sodium ☐☐☐ mmol/L Creatinine ☐☐☐.☐ µmol/L

Anaesthesia induction time & date: H H m m D D 0 M 2 0 1 4

Anaesthetic technique (*tick all that apply*)

☐ General ☐ Spinal ☐ Epidural ☐ Sedation / Local

Surgical procedure category (*single best answer*):

- ☐ Orthopaedic
- ☐ Obstetrics & Gynaecology
- ☐ Upper gastro-intestinal
- ☐ Hepato-biliary
- ☐ Head and neck
- ☐ Cardiac
- ☐ Thoracic (gut)
- ☐ Breast
- ☐ Urology & Kidney
- ☐ Lower gastro-intestinal
- ☐ Vascular
- ☐ Plastics / Cutaneous
- ☐ Thoracic (lung & other)
- ☐ Other

Severity of surgery	☐ Minor	☐ Intermediate	☐ Major	
Laparoscopic surgery		☐ Y	☐ N	
Cancer surgery		☐ Y	☐ N	
Surgical checklist used (eg WHO checklist)		☐ Y	☐ N	
Critical care immediately after surgery		☐ Y	☐ N	

Data entry staff use only

ISOS patient Identifier: ☐☐☐ ☐☐☐☐☐☐☐

Patient name: ..... Date of birth: dd/mm/yyyy

Outcome after surgery

Infection				
Superficial surgical site	Mild ☐	Moderate ☐	Severe ☐	None ☐
Deep surgical site	Mild ☐	Moderate ☐	Severe ☐	None ☐
Body cavity	Mild ☐	Moderate ☐	Severe ☐	None ☐
Pneumonia	Mild ☐	Moderate ☐	Severe ☐	None ☐
Urinary tract	Mild ☐	Moderate ☐	Severe ☐	None ☐
Bloodstream	Mild ☐	Moderate ☐	Severe ☐	None ☐
Cardiovascular				
Myocardial infarction	Mild ☐	Moderate ☐	Severe ☐	None ☐
Arrhythmia	Mild ☐	Moderate ☐	Severe ☐	None ☐
Pulmonary oedema	Mild ☐	Moderate ☐	Severe ☐	None ☐
Pulmonary embolism	Mild ☐	Moderate ☐	Severe ☐	None ☐
Stroke	Mild ☐	Moderate ☐	Severe ☐	None ☐
Cardiac arrest			Severe ☐	None ☐
Other				
Gastro-intestinal bleed	Mild ☐	Moderate ☐	Severe ☐	None ☐
Acute kidney injury	Mild ☐	Moderate ☐	Severe ☐	None ☐
Post-operative bleed		Moderate ☐	Severe ☐	None ☐
ARDS	Mild ☐	Moderate ☐	Severe ☐	None ☐
Anastomotic leak	Mild ☐	Moderate ☐	Severe ☐	None ☐
Other	Mild ☐	Moderate ☐	Severe ☐	None ☐

Treatment for post-operative complications:

Drug therapy, blood transfusion or parenteral nutrition	☐ Y	☐ N
Surgical or radiological procedure	☐ Y	☐ N
Critical care admission	☐ Y	☐ N

Hours in Post-Anaesthetic Care Unit after surgery	h h	
Days in critical care after surgery	d d	
Days in hospital after surgery	d d	
Status at 30 days after surgery	☐ Alive	☐ Dead

Data entry staff use only

ISOS patient Identifier: ☐☐☐ ☐☐☐☐☐☐☐

Appendix 2 CRF for VISION

VISION **ELIGIBILITY AND PRE-OPERATIVE ASSESSMENT** **FORM 1.1**

VISION #019 **Plate #001** **Visit #000**

PATIENT ID: Centre No. Patient No. **PATIENT INITIALS:** F M L **Date form completed** 20 year month day

1. Patient is ≥ 45 years of age, has had noncardiac surgery requiring overnight hospital admission and has received a general or regional anaesthetic. ☐ No ☐ Yes
2. Patient consents prior to or within the first 24hrs after surgery to participate in the VISION study including the 30 day and 1 year followup. ☐ No ☐ Yes
3. Patient previously enrolled in VISION. ☐ No ☐ Yes

Answers must be "yes" to question 1 & 2 and "no" to question 3 to be eligible for enrollment.

PREOPERATIVE ASSESSMENT (see back for definitions)

1. Date of Birth (year, month, day)
2. Male ☐ Female ☐
3. Weight ☐ kg ☐ lbs
4. Height ☐ cm ☐ in
5. Ethnicity: Code #
6. Is the patient living in a nursing home? ☐ No ☐ Yes
7. Patient requires assistance with ADL ☐ No ☐ Yes
8. Prior to hospitalization how many hours per day on average was patient bedridden?
9. History of tobacco use? ☐ No ☐ Yes
   - Type of tobacco use (check all that apply): ☐ Cigarettes ☐ Beedies ☐ Paan ☐ Chewing tobacco ☐ Cigars ☐ Pipes ☐ Snuff ☐ Sheesha/water pipe
   - Avg # per day of all tobacco products; Year started; Date of last use prior to surgery (year, month, day)

No Yes

10. Currently in atrial fibrillation? ☐ ☐
11. Not currently in atrial fibrillation, but prior history of atrial fibrillation? ☐ ☐
12. History of congestive heart failure? ☐ No ☐ Yes
13. History of coronary artery disease? ☐ No ☐ Yes
14. History of recent (i.e., ≤ 6 months) high-risk coronary artery disease? ☐ No ☐ Yes → (year, month, day) check most recent event: ☐ myocardial infarction ☐ acute coronary syndrome ☐ CCSC III ☐ CCSC IV
15. History of cardiac catheterization/revascularization?
    a. ≤ 12 months prior to surgery? ☐ No ☐ Yes → If Yes. please complete **Pre-op Cardiac Cath/Revasc Form 6.1**
    b. > 12 months prior to surgery? ☐ No ☐ Yes → date of most recent procedure (year, month) → ☐ Cardiac Cath only ☐ PCI → Stent ☐ No ☐ Yes → DES ☐ No ☐ Yes ☐ CABG
16. History of cardiac arrest? ☐ No ☐ Yes → date of most recent event (year, month)
17. Does the patient have known aortic stenosis? ☐ No ☐ Yes → please complete **Aortic Stenosis Form 7.1**
18. History of DVT/PE ? ☐ No ☐ Yes → date of most recent event (year, month) → ☐ DVT ☐ PE
19. History of cerebral vascular event? ☐ No ☐ Yes → date of most recent event (year, month) → ☐ Stroke ☐ TIA
20. History of obstructive sleep apnea? ☐ No ☐ Yes
21. History of peripheral vascular disease? ☐ No ☐ Yes
22. History of hypertension? ☐ No ☐ Yes
23. History of peptic ulcer disease in the previous 6 months? ☐ No ☐ Yes
24. History of COPD ? ☐ No ☐ Yes
25. History of diabetes? ☐ No ☐ Yes → year of diagnosis
26. Surgery performed: ☐ < 24hrs since acute event that led to need for surgery ☐ 24-72hrs since acute event that led to need for surgery ☐ all other surgeries
27. For FEMALEs, number of pregnancies → Pregnancies with Pre-Eclampsia; Pregnancies with Severe Pre-Eclampsia

Person completing form (please print) **Last Name** **First Initial** Investigator's Name Investigator's Signature VERSION 8 - FEB 6, 2009

VISION **PREOPERATIVE / HAEMODYNAMICS** **FORM 1.2**

VISION #019 Plate #002 Visit #000

PATIENT ID: Centre No. Patient No. **PATIENT INITIALS:** F M L **Date form completed** 20 year month day

PREOPERATIVE ASSESSMENT (continued)

1. Does the patient have "active" cancer? ☐ No ☐ Yes
2. Is the patient's surgery for cancer? ☐ No ☐ Yes
3. Does patient have metastatic disease? ☐ No ☐ Yes
4. Is the patient's surgery for an acute fracture? ☐ No ☐ Yes → date of fracture (month, day) type of fracture Code # (see back)
5. History of chronic pain? ☐ No ☐ Yes
6. Is patient on dialysis? ☐ No ☐ Yes
7. **Preoperative laboratory tests:**

a. NT-proBNP . ☐ pg/ml ☐ pmol/L ☐ not measured

b. Hemoglobin level ☐ g/L ☐ g/dL ☐ not measured

c. Most recent Creatinine . ☐ umol/L ☐ mg/dL ☐ not measured

d. Glucose level measured ☐ No ☐ Yes → . ☐ mmol/L ☐ mg/dL → ☐ lab ☐ finger-stick

IV dextrose/TPN running or active enteral feeds at time of glucose measurement? ☐ Yes ☐ No → # hrs since p.o. or any enteral intake

HAEMODYNAMICS:

1. Record pre-op vital signs measurements that are closest and prior to anesthesia induction

a. Blood pressure ___ / ___ (systolic / diastolic) mmHg b. Heart rate ___ bpm ☒

2. Systolic Blood Pressure **< 100 mmHg**

Time Period	No	Yes	Lowest value	Duration (min) < 90 mmHg	Duration (min) 90 - 99 mmHg	Rx code see back
Intraop	☐	☐				
PACU	☐	☐				
OR day post PACU	☐	☐				
POD 1	☐	☐				
POD 2	☐	☐				
POD 3	☐	☐				
POD 4 to discharge	☐	☐				

Lowest value *of Longest* Hypotensive Event

3. Systolic Blood Pressure **> 160 mmHg**

No	Yes	Highest value	Duration (min) 161 - 199 mmHg	Duration (min) ≥ 200 mmHg
☐	☐			
☐	☐			
☐	☐			
☐	☐			
☐	☐			
☐	☐			

Start date of *Longest* Hypotensive Event 20 year month day

4. Heart Rate **< 55 bpm**

Time Period	No	Yes	Lowest Value	Duration (min) < 45 bpm	Duration (min) 45 - 54 bpm	Rx code see back
Intraop	☐	☐				
PACU	☐	☐				
OR day post PACU	☐	☐				
POD 1	☐	☐				
POD 2	☐	☐				
POD 3 to discharge	☐	☐				

Lowest value *of Longest* Bradycardia Event

5. Heart Rate **> 100 bpm**

No	Yes	Highest value	Duration (min) 101 - 140 bpm	Duration (min) > 140 bpm
☐	☐			
☐	☐			
☐	☐			
☐	☐			
☐	☐			
☐	☐			

Start date of *Longest* Bradycardia Event 20 year month day

6. Respiratory Rate **< 10/min** POD 0-4 ☐ No ☐ Yes Lowest value ___ Duration (min) ___ Rx code ___

7. Oximetry **< 90%** POD 0-4 ☐ No ☐ Yes Lowest value ___ Duration (min) ___ Rx code ___

Person completing form (please print) **Last Name** **First Initial** Investigator's Name Investigator's Signature

VERSION 3 - Apr 22, 2009

VISION **OPERATIVE ASSESSMENT** **FORM 2.1**

VISION #019 Plate #005 Visit #001

PATIENT ID: Centre No. Patient No. **PATIENT INITIALS:** F M L **Date form completed** 20 year month day

PREOPERATIVE CARDIAC MEDICATIONS Indicate any use during the following periods prior to surgery:

	≤ 24 hrs		> 24 hrs to 7 days	
	No	**Yes**	**No**	**Yes**
1. Aspirin	☐	☐	☐	☐
2. Insulin	☐	☐	☐	☐
3. Oral diabetic drug	☐	☐	☐	☐
4. Long-acting nitrate	☐	☐	☐	☐
5. Oral Anticoagulant	☐	☐	☐	☐
6. ACEI/ARB	☐	☐	☐	☐
7. Beta-blocker	☐	☐	☐	☐
8. Non-statin cholesterol lowering drug	☐	☐	☐	☐
9. Statin	☐	☐	☐	☐
10. Ticlopidine or Plavix	☐	☐	☐	☐

	≤ 24 hrs		>24 hrs to 7 days	
	No	**Yes**	**No**	**Yes**
11. COX-2 Inhibitor	☐	☐	☐	☐
12. NSAID/ non-COX-2 Inhibitor	☐	☐	☐	☐
13. Alpha 2 agonist	☐	☐	☐	☐
14. Rate Controlling CCB	☐	☐	☐	☐
15. Dihydropyridine CCB	☐	☐	☐	☐
16. Prophylactic subc antithrombotic agent	☐	☐	☐	☐
17. Therapeutic subc or IV antithrombotic agent	☐	☐	☐	☐
18. Nicotine Replacement	☐	☐	☐	☐
19. Non-nicotine smoking cessation drugs	☐	☐	☐	☐

INTRAOPERATIVE AND POSTOPERATIVE ASSESSMENT

1. TYPE OF SURGERY PERFORMED (check all that apply) (see back for definitions)

Vascular Surgery
- ☐ thoracic aorta reconstruction
- ☐ aorto-iliac reconstruction
- ☐ peripheral vascular reconstruction without aortic cross-clamping
- ☐ extracranial cerebrovascular surgery
- ☐ EVAR

General Surgery
- ☐ complex visceral resection
- ☐ partial or total colectomy, or stomach surgery
- ☐ other intra-abdominal surgery
- ☐ major head and neck resection for non-thyroid tumor

Thoracic Surgery
- ☐ pneumonectomy
- ☐ lobectomy
- ☐ other thoracic surgery

Major Urology or Gynecology
- ☐ visceral resection
- ☐ cytoreductive surgery
- ☐ hysterectomy
- ☐ radical hysterectomy
- ☐ radical prostatectomy
- ☐ transurethral prostatectomy

Major Orthopedic Surgery
- ☐ major hip or pelvic surgery
- ☐ internal fixation of femur
- ☐ knee arthroplasty
- ☐ above knee amputation
- ☐ lower leg amputation

Major Neurosurgery
- ☐ craniotomy
- ☐ major spine surgery

Other Surgeries
- ☐ low risk surgeries

2. Surgical technique: (check all that apply) ☐ Endoscopic ☐ Open

3. Was surgery reported as minimally invasive? No ☐ Yes ☐

4. Date of hospital admission year month day

5. Date of surgery year month day

6. Time of surgery Start : (24 hr clock) End : (24 hr clock)

7. Did patient receive **any of the following** post surgery?

	No	Yes	if yes # days
a. Patient Controlled Analgesia	☐	☐	→
b. Continuous Nerve Block	☐	☐	→
c. Epidural Opioid Analgesia	☐	☐	→
d. Epidural Local Analgesia	☐	☐	→
e. Topical/IM/IV/SC opioids	☐	☐	→

8. Type of anaesthetic **(check all that apply)**
- ☐ general
- ☐ spinal
- ☐ nerve block
- ☐ epidural → ☐ lumbar ☐ thoracic → Local anaesthetic in epidural ☐ No ☐ Yes
- ☐ nitrous oxide

Person completing form (please print) **Last Name** **First Initial** Investigator's Name Investigator's Signature

VERSION 7- June 10, 2008

VISION **DISCHARGE ASSESSMENT** **FORM 3.1**

VISION #019 Plate #010 Visit #002

PATIENT ID: Centre No. Patient No. **PATIENT INITIALS:** F M L **Date form completed** 20 year month day

HOSPITAL DISCHARGE (see back for explanation)

1. Date of discharge 20 year month day

2. Was patient transferred to another facility? **No** ☐ **Yes** ☐ → Complete **Patient Transfer Form 8.1**

3. Number of nights in ICU/CCU

POSTOPERATIVE TROPONIN T *or* TROPONIN T hs RESULTS (see back [X]) specify → ☐ ng/L ***TnT hs (5th generation)*** ☐ ug/L ***TnT (4th generation)***

	Year	*Month*	*Day*	*24 hour clock*	*check if <*	
1. 6 - 12 hours post-op				:	☐	.
2. On Day 1 post-op				:	☐	.
3. On Day 2 post-op				:	☐	.
4. On Day 3 post-op				:	☐	.

MEDICATIONS IN HOSPITAL

	Any use during first 3 days post op **No**	**Yes**	At discharge **No**	**Yes**
1. Aspirin	☐	☐	☐	☐
2. Insulin	☐	☐	☐	☐
3. Oral diabetic drug or other injectables	☐	☐	☐	☐
4. Long-acting nitrate	☐	☐	☐	☐
5. Oral Anticoagulant	☐	☐	☐	☐
6. ACEI/ARB	☐	☐	☐	☐
7. Beta-blocker	☐	☐	☐	☐
8. Non-statin cholesterol lowering drug	☐	☐	☐	☐
9. Statin	☐	☐	☐	☐
10. Ticlopidine or Plavix	☐	☐	☐	☐
11. COX-2 Inhibitor	☐	☐	☐	☐
12. NSAID/ non-COX-2 Inhibitor	☐	☐	☐	☐
13. Alpha 2 agonist	☐	☐	☐	☐
14. Rate Controlling CCB	☐	☐	☐	☐
15. Dihydropyridine CCB	☐	☐	☐	☐
16. Prophylactic subc antithrombotic agent	☐	☐	☐	☐
17. Therapeutic subc or IV antithrombotic agent	☐	☐	☐	☐
18. Nicotine Replacement	☐	☐	☐	☐
19. Non-nicotine smoking cessation drugs	☐	☐	☐	☐
20. Naloxone (see back)	☐	☐		

CLINICAL EVENTS DURING HOSPITALIZATION

If patient is discharged after 30 day follow up do not include events already reported on 30 Day Follow up Form 4.1)

	No	**Yes**	If Yes, complete Report Number (s)
1. Death	☐	☐	010
2. Myocardial Infarction	☐	☐	02 ; 02
3. Non-fatal cardiac arrest	☐	☐	03 ; 03
4. Stroke	☐	☐	04 ; 04
5. Leg or arm DVT/PE	☐	☐	05 ; 05
6. Bleeding	☐	☐	06 ; 06
7. New acute renal failure (requiring dialysis)	☐	☐	07 ; 07
8. Sepsis/Infection	☐	☐	08 ; 08
9. Pneumonia	☐	☐	09 ; 09
10. New clinically important atrial fibrillation	☐	☐	10 ; 10
11. Congestive heart failure	☐	☐	11 ; 11
12. Cardiac catheterization	☐	☐	12 ; 12
13. PCI	☐	☐	13 ; 13
14. CABG	☐	☐	14 ; 14
15. Amputation (see back)	☐	☐	15 ; 15

Person completing form (please print) _____ **Last Name** _____ **First Initial** Investigator's Name _____ Investigator's Signature _____

VERSION 7 - Apr 26, 2010

VISION **30 DAY FOLLOW-UP** **FORM 4.1**

VISION #019 Plate #020 Visit #003

PATIENT ID: Centre No. Patient No. **PATIENT INITIALS:** F M L **Date form completed** 20 year month day

1. 30 day post-op date 20 year month day

2. Was the 30 day follow up completed? ☐ Yes ☐ No → Reason: _____

3. Is patient living in a nursing home? ☐ No ☐ Yes

4. From date of surgery up to 30 days postop, complete:
   a. Highest serum creatinine level . ☐ umol/L ☐ mg/dL ☐ not measured
   b. Lowest Hemoglobin level ☐ g/L ☐ g/dL ☐ not measured
   c. RBCs transfused # total units

5. Has the patient been rehospitalized since discharge?
   No ☐ Yes ☐ → Date year month day
   Was admission for vascular reasons? (see definition on back) ☐ No ☐ Yes

MEDICATIONS AT 30 DAY FOLLOW UP

	No	Yes
1. Aspirin	☐	☐
2. Insulin	☐	☐
3. Oral diabetic drugs	☐	☐
4. Long-acting nitrate	☐	☐
5. Oral Anticoagulant	☐	☐
6. ACEI/ARB	☐	☐
7. Beta-blocker	☐	☐
8. Non-statin cholesterol lowering drug	☐	☐
9. Statin	☐	☐
10. Ticlopidine or Plavix	☐	☐
11. COX-2 Inhibitor	☐	☐
12. NSAID/ non-COX-2 Inhibitor	☐	☐
13. Alpha 2 agonist	☐	☐
14. Rate Controlling CCB	☐	☐
15. Dihydropyridine CCB	☐	☐
16. Prophylactic subc antithrombotic agent	☐	☐
17. Therapeutic subc or IV antithrombotic agent	☐	☐
18. Nicotine Replacement	☐	☐
19. Non-nicotine smoking cessation drugs	☐	☐

CURRENT TOBACCO USE

☐ No ☐ Yes

Type of tobacco use (check all that apply): ☐ Cigarettes ☐ Beedies ☐ Paan ☐ Chewing tobacco ☐ Cigars ☐ Pipes ☐ Snuff ☐ Sheesha/water pipe

Avg # per day of all tobacco products

Date started after surgery year month day

CLINICAL EVENTS UP TO 30 DAYS AFTER SURGERY
(Do not include events already reported on Discharge Form 3.1)

	No	Yes	If Yes, complete Report Number (s)
1. Death	☐	☐	010
2. Myocardial Infarction	☐	☐	02 ; 02
3. Non-fatal cardiac arrest	☐	☐	03 ; 03
4. Stroke	☐	☐	04 ; 04
5. Leg or arm DVT/PE	☐	☐	05 ; 05
6. Bleeding	☐	☐	06 ; 06
7. New acute renal failure (requiring dialysis)	☐	☐	07 ; 07
8. Sepsis/Infection	☐	☐	08 ; 08
9. Pneumonia	☐	☐	09 ; 09
10. New clinically important atrial fibrillation	☐	☐	10 ; 10
11. Congestive heart failure	☐	☐	11 ; 11
12. Cardiac catheterization	☐	☐	12 ; 12
13. PCI	☐	☐	13 ; 13
14. CABG	☐	☐	14 ; 14
15. Amputation	☐	☐	15 ; 15

Person completing form (please print) **Last Name** **First Initial** Investigator's Name Investigator's Signature

VERSION 5 -Feb 24, 2009

VISION **ONE YEAR FOLLOW-UP** **FORM 5.1**

VISION #019 Plate #025 Visit #004

PATIENT ID: Centre No. Patient No. **PATIENT INITIALS:** F M L **Date form completed** 20 year month day

1. 1 year post-operative date: 20 year month day
2. Was the 1 year follow-up completed? ☐ Yes ☐ No → Reason: _____
3. Is patient living in a nursing home? ☐ Yes ☐ No
4. Has the patient been rehospitalized between the 30 day and 1 year follow-up?

☐ No ☐ Yes → Date year month day → # days in hospital

If Yes, was admission for vascular reasons? ☐ No ☐ Yes

MEDICATIONS AT ONE YEAR FOLLOW UP

	No	Yes
1. Aspirin	☐	☐
2. Insulin	☐	☐
3. Oral diabetic drugs or other injectable	☐	☐
4. Long-acting nitrate	☐	☐
5. Oral Anticoagulant	☐	☐
6. ACEI/ARB	☐	☐
7. Beta-blocker	☐	☐
8. Non-statin cholesterol lowering drug	☐	☐
9. Statin	☐	☐
10. Ticlopidine or Plavix	☐	☐
11. COX-2 Inhibitor	☐	☐
12. NSAID/ non-COX-2 Inhibitor	☐	☐
13. Alpha 2 agonist	☐	☐
14. Rate Controlling CCB	☐	☐
15. Dihydropyridine CCB	☐	☐
16. Prophylactic subc antithrombotic agent	☐	☐
17. Therapeutic subc or IV antithrombotic agent	☐	☐
18. Nicotine Replacement	☐	☐
19. Non-nicotine smoking cessation drugs	☐	☐

CURRENT TOBACCO USE

☐ No ☐ Yes

Type of tobacco use (check all that apply) ☐ Cigarettes ☐ Beedies ☐ Paan ☐ Chewing tobacco ☐ Cigars ☐ Pipes ☐ Snuff ☐ Sheesha/water pipe

Avg # per day of all tobacco products

Date started after surgery year month day

CLINICAL EVENTS BETWEEN 30 DAYS AND ONE YEAR FOLLOW-UP

	No	Yes	If Yes, complete Report Number (s)
1. Death	☐	☐	010
2. Myocardial Infarction	☐	☐	02 ; 02
3. Non-fatal cardiac arrest	☐	☐	03 ; 03
4. Stroke	☐	☐	04 ; 04
5. Leg or arm DVT/PE	☐	☐	05 ; 05

6. Is patient on dialysis? No ☐ Yes ☐
7. Congestive heart failure ☐ ☐ 11 ; 11
8. Cardiac catheterization ☐ ☐ 12 ; 12
9. PCI ☐ ☐ 13 ; 13
10. CABG ☐ ☐ 14 ; 14
11. Amputation ☐ ☐ 15 ; 15

	No	Yes	year	month	day
12. New diagnosis of diabetes since surgery	☐	☐			
13. New diagnosis of cancer since surgery	☐	☐			
14. Diagnosis of recurrent cancer since surgery	☐	☐			
15. New diagnosis of dementia since surgery	☐	☐			
16. Incisional site pain	☐	☐			

→ Complete Chronic Pain Form 5.2

Person completing form (please print) **Last Name** **First Initial** **Investigator's Name** _____ **Investigator's Signature** _____

Version 9: 2012 Jun 01 VERSION 6 -October 9, 2009